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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/601,171	07/28/2000	Michael Buschle	0652.2100000	6961

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EXAMINER	
NAVARRO, ALBERT MARK	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 11/12/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/601,171	Applicant(s) Buschle et al
	Examiner Mark Navarro	Art Unit 1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 17-34 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 17-34 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Applicant's preliminary amendment filed July 28, 2000 (Paper Number 3) has been received and entered. Claims 1-16 have been canceled and new claims 17-34 have been added, consequently claims 17-34 are pending in the instant application.

SEQUENCE LISTING

Applicant's second submission of a computer readable copy of the sequences on November 2, 2001 (Paper Number 8) has been received, however the disk appears to have been prematurely separated. Applicant's are requested to provide another copy of the disk in response to this Office Action. The Examiner apologizes for this inconvenience.

Claim Rejections - 35 USC § 112

1. Claim 32 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claim is directed to a vaccine wherein the peptide is derived from a tumor antigen.

Yamana et al (Japanese Journal of Cancer and Chemotherapy, Sept. 2000, Vol. 27, No. 10, pp 1477-1488) set forth of the recent identification of several possible tumor antigens.

Yamana et al further set forth that recent studies have reported that many tumors escape from CTL recognition by downregulation of HLA class I expression. Moreover, most cancer cells produce suppressor agents against the immune system. Yamana et al conclude that "we must resolve major problems to produce successful cancer vaccine therapy soon."

A vaccine "must by definition trigger an immunoprotective response in the host vaccinated; mere antigenic response is not enough." In re Wright, 999 F.2d 1557,1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993).

Given that successful cancer vaccine therapy still has to resolve major problems as evidenced by the teaching of Yamana et al, one of skill in the art would be forced into excessive experimentation to practice the broadly claimed invention in view of the lack of working examples, lack of guidance, and lack of success of others in the art.

2. Claims 17-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are vague and indefinite in the recitation of "low concentration of inorganic salts." One of skill in the art would be unable to determine the metes and bounds of the claimed invention. For instance, at what concentration is a salt considered to be "low?" Likewise, at what level does it become medium or high? Furthermore, is it based on weight per weight, weight per

volume? Without a clear definition as to the metes and bounds of the phrase "low concentration of inorganic salts" one of skill in the art would be unable to determine the metes and bounds of the claimed invention.

3. Claims 17-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are vague and indefinite in the recitation of "highly purified." One of skill in the art would be unable to determine the metes and bounds of the claimed invention. For instance, at what level of purity is the peptide considered to be "highly purified?" Likewise, at what level does it become medium or low? Without a clear definition as to the metes and bounds of the phrase "highly purified" one of skill in the art would be unable to determine the metes and bounds of the claimed invention.

4. Claims 18-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are vague and indefinite in the recitation of a "substantially free." The metes and bounds of such a limitation can not be determined by one of skill in the art. For instance,

what level of contaminants may be present and still be considered as "substantially free?" Similarly, at what level does their presence rise to the level of no longer "substantially free?" Without a clear definition as to the metes and bounds of the term "substantially free" one of skill in the art would be unable to determine the metes and bounds of the claimed invention.

5. Claims 25 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is vague and indefinite in the recitation of "slightly hypotonic" The metes and bounds of such a limitation can not be determined by one of skill in the art. For instance, what range would be considered as "slightly hypotonic?" Similarly, at what level does hypotonicity rise to the level of moderately/high "hypotonic?" Without a clear definition as to the metes and bounds of the term "slightly hypotonic" one of skill in the art would be unable to determine the metes and bounds of the claimed invention.

6. Claim 32 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is vague and indefinite in the use of the phrase "derived from." Since it is unclear if the antigens are undergoing any kind of chemical modification as implied by the recitation of "derived from." Since it is unclear how the antigens are to be derived as referred to in the claims, there is no way for the person of skill in the art to ascribe a discrete and identifiable definition to said phrase.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

7. Claims 17-32 are rejected under 35 U.S.C. 102(e) as being anticipated by Hauser et al.

The claims are directed to a vaccine containing one or more synthetic or highly purified natural peptides as antigen(s) as well as one or more adjuvants, characterized in that it is present as a solution or emulsion which is free from inorganic salt ions or has a low concentration of inorganic ions.

Hauser et al (U.S. Patent Number 5,776,468) disclose of a vaccine comprising a purified peptide antigen in combination with an adjuvant in a solution. Hauser et al further disclose of the vaccine containing sorbitol. (See claims).

It is noted that the claims also recite that the solution is "free from inorganic salt ions or has a low concentration of inorganic ions." Given that the claims of U.S. Patent Number 5,766,468, do not recite the presence of any inorganic salt ions, the composition disclosed by Hauser et al is deemed to be "free from inorganic salt ions or has a low concentration of inorganic ions."

Since the Patent office does not have the facilities for examining and comparing applicants' product with the product of the prior art reference, the burden is on applicants to show an unobvious distinction between the material structural and functional characteristics of the claimed product and the product of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

8. Claims 17-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Schmidt et al.

The claims are directed to a vaccine containing one or more synthetic or highly purified natural peptides as antigen(s) as well as one or more adjuvants, characterized in that it is present as a solution or emulsion which is free from inorganic salt ions or has a low concentration of inorganic ions, and wherein the adjuvant is polyarginine.

Schmidt et al (WO 97/30721) disclose of pharmaceutical compositions containing a purified peptide and further containing an adjuvant, wherein the adjuvant is polyarginine. (See abstract).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro, whose telephone number is (703) 306-3225. The examiner can be reached on Monday - Thursday from 8:00 AM - 6:00 PM. The examiner can be reached on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Lynette Smith can be reached at (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 1645 by facsimile transmission. Papers should by faxed to Group 1645 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the official Gazette 1096 OG 30 (November 15, 1989). The CMI Fax Center number is (703) 308-4242.

Mark Navarro

Primary Examiner

November 6, 2002